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08/858389

SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
08/858,389	05/19/97	FOERSTER	A-102500N

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EXAMINER	
KOO, B	
ART UNIT	PAPER NUMBER
3733	7

DATE MAILED: 10/01/98

Please find below a communication from the EXAMINER in charge of this application.

Commissioner of Patents

See enclosed Office action.

Office Action Summary

Application No.

08/858,389

Applicant(s)

Seth A. Foerster et al.

Examiner

Benjamin Koo

Group Art Unit

3733



☒ Responsive to communication(s) filed on Jul 17, 1998

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1, 4-6, 9-12, 14-18, and 35-44 is/are pending in the application.

Of the above, claim(s) 6, 10-12, 15, 35, 36, and 42 is/are withdrawn from consideration.

☒ Claim(s) 44 is/are allowed.

☒ Claim(s) 1, 4, 5, 9, 16-18, 37-40, and 43 is/are rejected.

☒ Claim(s) 14 and 41 is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 2-3

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Election/Restriction

1. Claims 19-34 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected species. Election was made **without** traverse in Paper No. 6. Furthermore, claims 6, 10-12, 15, 35, 36, and 42 have also been withdrawn from consideration as also being drawn to a non-elected species, but will be considered upon allowance of a generic claim, currently claims 1 and 38 are generic.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the tube lumen adapted to receive a plurality of marker elements as set forth in claim 18 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Specification

3. Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure

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of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:

- (1) if a machine or apparatus, its organization and operation;
- (2) if an article, its method of making;
- (3) if a chemical compound, its identity and use;
- (4) if a mixture, its ingredients;
- (5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

4. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of 37 CFR 1.71(a)-(c):

(a) The specification must include a written description of the invention or discovery and of the manner and process of making and using the same, and is required to be in such full, clear, concise, and exact terms as to enable any person skilled in the art or science to which the invention or discovery appertains, or with which it is most nearly connected, to make and use the same.

(b) The specification must set forth the precise invention for which a patent is solicited, in such manner as to distinguish it from other inventions and from what is old. It must describe completely a specific embodiment of the process, machine, manufacture, composition of matter or improvement invented, and must explain the mode of operation or principle whenever applicable. The best mode contemplated by the inventor of carrying out his invention must be set forth.

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(c) In the case of an improvement, the specification must particularly point out the part or parts of the process, machine, manufacture, or composition of matter to which the improvement relates, and the description should be confined to the specific improvement and to such parts as necessarily cooperate with it or as may be necessary to a complete understanding or description of it.

The specification is objected to under 37 CFR 1.71 because it fails to provide adequate written description and failing to be completely enabling, with regard to embodiment of Fig. 12 in which multiple marker elements are supposedly used. Fig. 12 only shows 2 elements and only 1 has been shown in the delivery device, it is unclear as to how a plurality of marker elements would be individually ejected and how they are "preloaded".

Claim Rejections - 35 USC § 112

6. Claim 18 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons set forth in the previous paragraphs of this office action.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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8. Claims 1, 4, 5, 9, 16, 17, 37-40, and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Komiya '576 in view of Isse '262. Komiya shows a device comprising: a discrete marker element (11), a deliver apparatus or tube lumen (10), a deployment actuator connector (19), a forming die (21), the marker element being able to travel along the tube, and a mandrel (20), but does not show the cutting tip or the vacuum. As is known in the art, devices such as Komiya are often used in combination with endoscopes which deliver the devices to the appropriate site. Isse shows such an endoscope which can be used to deliver various devices to a surgical site, Isse further show a cutting tip (18) and the use of a vacuum. It would have been obvious to one of ordinary skill at the time the invention was made to have used Komiya in conjunction with Isse because both devices are known to be used with one another in the art. The cutting edge of Isse is obviously used to pierce the skin to get to a location and the vacuum can be use to extract debris often associated with this kind of procedure. It is further obvious and inherent for these devices to be used in combination with various types of visualization and guidance systems as known in the art, but even so, in the claims, absent any structure to define such additional elements, these limitations will not be given weight.

Allowable Subject Matter

9. Claim 14 and 41 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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10. Claim 44 is allowed.

11. The following is an examiner's statement of reasons for allowance: the prior art of record does not show a device having an axial deployment actuator extending proximal of the proximal portion of the member and distally of the distal portion of the member, further showing the failure point type actuator as substantially claimed by the applicant.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

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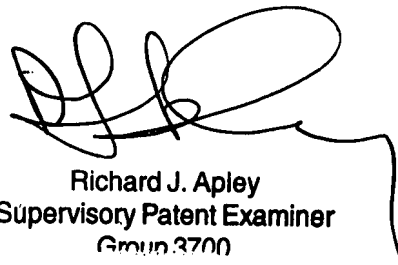
13. Any inquiry concerning the specifics of this communication should be directed to Examiner Ben Koo who can be reached Monday through Friday from 8:30 am to 6:00 pm. Inquiries of a general nature should be directed to the Group 3730 receptionist. Official responses can be filed 24 hours a day to the Official fax number listed below, subject to the provisions of 37 C.F.R. 1.6(d). Unofficial faxes which are meant for discussion purposes only should be sent to the Unofficial Fax number below; it is strongly suggested that the Examiner be contacted directly before sending any Unofficial Fax.

Contact numbers:

Examiner Koo	703-308-2657
Group 3730 Receptionist	703-308-0858
Group 3730 Official Fax	703-308-3590
Art Unit 3733 Unofficial Fax	703-308-0758

bk

September 25, 1998



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